

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

May 2011

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male
M1
M2
М3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

	Male		Female					
M1	M2	М3	F1	F2	F3			
M4	M5		F4	F5				

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 3

Report Date: 05/17/2011

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052030401 058814806	N/A 01/29/03	N/A 727	0(0) 50(3)	0(0) 28(665)	N/A 606.4	TEF evaluation (PCB 118) 3,3',4,4'-Tetrachloroazobenzene
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052030401 058814806	03/26/04 01/30/03	733 727	52(5) 50(5)	21(616) 25(652)	383.5 385.7	TEF evaluation (PCB 118) 3,3',4,4'-Tetrachloroazobenzene

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 4

			Male				Female	
#All Organs: Benign Tumors								
			40/50 (80%)			43/52 (83%)	40/50 (80%)	
Overall Incidence	Total	40/50 (80%)	Mean 80%	SD 0%	Total	83/102 (81.37%)	Mean 81.35%	SD 1.9%
#All Organs: Malignant Tumors								
			9/50 (18%)			15/52 (29%)	13/50 (26%)	
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	28/102 (27.45%)	Mean 27.42%	SD 2.01%
#All Organs: Malignant and Benign Tu	umors		44/50 (88%)			48/52 (92%)	44/50 (88%)	
Overall Incidence	Total	44/50 (88%)	Mean 88%	SD 0%	Total	92/102 (90.2%)	Mean 90.15%	SD 3.05%
#All Organs: Hemangiosarcoma Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	1/52 (2%) 1/102 (0.98%)	0/50 (0%) Mean 0.96%	SD 1.36%
	TOLAI	1/30 (2/8)						
#All Organs: Hemangiosarcoma or He	emangioma		(20)			(00)	2(72 (22))	
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	1/52 (2%) 1/102 (0.98%)	0/50 (0%) Mean 0.96%	SD 1.36%
#All Organs: Histiocytic Sarcoma			0/50 (0%)			1/52 (2%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.96%	SD 0.05%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 5

			Male				Female					
#All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated												
			1/50 (2%)			0/52 (0%)	1/50 (2%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%				
#All Organs:			or Undifferentiated Cell									
			1/50 (2%)			2/52 (4%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%				
*Adrenal Cortex: Adenoma			1/50 (2%)			2/52 (4%)	1/50 (2%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/102 (2.94%)	Mean 2.92%	SD 1.31%				
*Adrenal Cortex: Carcinoma Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/52 (2%) 1/102 (0.98%)	0/50 (0%) Mean 0.96%	SD 1.36%				
Overali incidence	ı olal	0/50 (0%)	iviean 0%	SD 0%	ı Olal	1/102 (0.96%)	iviean 0.96%	עפ				
*Adrenal Medulla: Pheochromocytoma Be	enign											
Overall Incidence	Total	5/50 (10%)	5/50 (10%) Mean 10%	SD 0%	Total	3/52 (6%) 6/102 (5.88%)	3/50 (6%) Mean 5.88%	SD 0.16%				
*Adrenal Medulla: Pheochromocytoma: B	Benign, Complex,	Malignant, NOS	5/50 (10%)			3/52 (6%)	3/50 (6%)					
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	6/102 (5.88%)	Mean 5.88%	SD 0.16%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 6

(2%)

SD 1.41%

Mean 1%

1/50

(0%)

0/52

Total

1/102 (0.98%)

Report Date: 05/17/2011

			Male				Female	
Brain: Astrocytoma Benign								
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/52 (0%) 0/102 (0%)	0/50 (0%) Mean 0%	SD 0%
	10tai	1/30 (276)	IVIEdII 270			0/102 (0%)		טעט עס
Brain: Oligodendroglioma, Glion	na, or Astrocy	toma						
			1/50 (2%)			0/52 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
#Eye: Schwannoma Malignant Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/52 (0%) 0/102 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenun Carcinoma			0/50 (0%)			0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unspe Carcinoma								
		0/50 (00/)	0/50 (0%)			0/52 (0%)	1/50 (2%)	05
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%

SD 0%

(0%)

0/50

Mean 0%

Total

0/50 (0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 7

			Male				Female	
*Islets, Pancreatic: Adenoma								
			2/50 (4%)			0/52 (0%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma			2/50 (4%)			0/52 (0%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma						•••••		
			0/50 (0%)			0/52 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%
*Liver: Cholangiocarcinoma			2(22)			2/22 (221)		
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/52 (0%) 1/102 (0.98%)	1/50 (2%) Mean 1%	SD 1.41%
		` '						
*Liver: Cholangioma			0/50 (00)			4/50 (00()	0(50 (00))	
Overall Incidence	Total	0/50 (00/)	0/50 (0%)	CD 00/	Total	1/52 (2%)	0/50 (0%)	CD 4.260/
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
*Liver: Hepatocellular Adenoma			0/50 /08/			0/50 (00/)	2/50 /40/	
Overall Incidence	Total	0/50 (09/)	0/50 (0%)	SD 00/	Total	0/52 (0%)	2/50 (4%) Mean 2%	SD 2.83%
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 8

			Male				Female				
*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma											
•	•		0/50 (0%)			0/52 (0%)	2/50 (4%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 2%	SD 2.83%			
Liver: Hepatocellular Carcino											
			0/50 (0%)			0/52 (0%)	2/50 (4%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 2%	SD 2.83%			
*Lung: Alveolar/Bronchiolar A	denoma		1/50 (2%)			0/51 (0%)	0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/101 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar C	arcinoma		1/50 (2%)			0/51 (0%)	0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/101 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar C			oma								
Overall Incidence	Total	2/50 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	0/51 (0%) 0/101 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Mammary Gland: Adenoma											
O	Tatal	0/50 (00/)	0/50 (0%)	CD 00/	Tatal	0/52 (0%)	1/50 (2%)	CD 4 440/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 9

			Male				Female			
#Mammary Gland: Carcinoma										
		- / /	0/50 (0%)			2/52 (4%)	4/50 (8%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/102 (5.88%)	Mean 5.92%	SD 2.94%		
#Mammary Gland: Carcinoma or Adenom			0/50 (0%)			2/52 (4%)	5/50 (10%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	7/102 (6.86%)	Mean 6.92%	SD 4.35%		
#Mammary Gland: Fibroadenoma										
			0/50 (0%)			25/52 (48%)	31/50 (62%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	56/102 (54.9%)	Mean 55.04%	SD 9.85%		
#Mammary Gland: Fibroma, Fibroadenom	na or Adenoma									
		- / /)	0/50 (0%)			25/52 (48%)	31/50 (62%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	56/102 (54.9%)	Mean 55.04%	SD 9.85%		
#Mammary Gland: Fibroma, Fibroadenom										
			0/50 (0%)			27/52 (52%)	32/50 (64%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	59/102 (57.84%)	Mean 57.96%	SD 8.54%		
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary									
			1/50 (2%)			0/52 (0%)	0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 10

			Male				Female				
≄Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma											
-			1/50 (2%)			0/52 (0%)	0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%			
#Oral Mucosa: Squamous Cell Carcin	oma		1/50 (2%)			0/52 (0%)	0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%			
*Ovary: Granulosa Cell Tumor	Malignant										
						0/52 (0%)	1/50 (2%)				
Overall Incidence					Total	1/102 (0.98%)	Mean 1%	SD 1.41%			
*Ovary: Granulosa Cell Tumor:	Benign, Maligna	ınt, NOS				0/52 (00/)	4/50 (20/)				
Overall Incidence					Total	0/52 (0%) 1/102 (0.98%)	1/50 (2%) Mean 1%	SD 1.41%			
*Ovary: Luteoma											
Overall Incidence					Total	1/52 (2%) 1/102 (0.98%)	0/50 (0%) Mean 0.96%	SD 1.36%			
*Pancreas: Adenoma											
		0/50 (4004)	9/50 (18%)	25		0/52 (0%)	0/50 (0%)	00.007			
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 11

			Male			Female					
*Pancreas: Carcinoma											
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/52 (0%) 1/102 (0.98%)	1/50 (2%) Mean 1%	SD 1.41%			
*Pancreas: Carcinoma or Adenoma											
Overall Incidence	Total	9/50 (18%)	9/50 (18%) Mean 18%	SD 0%	Total	0/52 (0%) 1/102 (0.98%)	1/50 (2%) Mean 1%	SD 1.41%			
*Parathyroid Gland: Adenoma											
Overall Incidence	Total	1/43 (2.33%)	1/43 (2%) Mean 2.33%	SD 0%	Total	0/47 (0%) 0/93 (0%)	0/46 (0%) Mean 0%	SD 0%			
#Peripheral Nerve: Schwannoma Malignant			0/50 (0%)			0/52 (0%)	1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%			
#Peripheral Nerve: Schwannoma: Benign, Mal											
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/52 (0%) 1/102 (0.98%)	1/50 (2%) Mean 1%	SD 1.41%			
*Pituitary Gland: Pars Distali Adenoma											
Overall Incidence	Total	13/50 (26%)	13/50 (26%) Mean 26%	SD 0%	Total	17/52 (33%) 30/102 (29.41%)	13/50 (26%) Mean 29.35%	SD 4.73%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 12

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma												
			0/50 (0%)			2/52 (4%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%				
*Pituitary Gland: Pars Distal Carcinoma or Adenoma												
			13/50 (26%)			19/52 (37%)	13/50 (26%)					
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	32/102 (31.37%)	Mean 31.27%	SD 7.45%				
*Pituitary Gland: Pars Interm Adenoma												
			0/50 (0%)			0/52 (0%)	1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%				
*Pituitary Gland: Pars Interm Carcinoma or Adenoma			0/50 (0%)			0/52 (0%)	1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%				
*Prostate: Adenoma												
			5/50 (10%)									
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%								
*Prostate: Carcinoma or Adenoma			F/F0 (400)									
Overall Incidence	Total	E/EO (400/)	5/50 (10%)	CD 00/								
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 13

			Male				Female					
*Salivary Glands: Schwannoma Malignant												
_			1/50 (2%)			0/51 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/101 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Rhabdomyosarcoma												
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/52 (0%) 1/102 (0.98%)	1/50 (2%) Mean 1%	SD 1.41%				
#Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyoma		0/50 (0%)			0/52 (0%)	1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 1%	SD 1.41%				
#Skin: Basal Cell Adenoma			1/50 (2%)			0/52 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma or I	Basosquamous	Tumor Benign										
		•	1/50 (2%)			0/52 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma, Ba	sosquamous Tu	umor Benign, or Tricho	-			0/50 (00)	0/50 (00/)					
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/52 (0%) 0/102 (0%)	0/50 (0%) Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Page: 14

	Ma						Female				
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma											
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/52 (0%) 0/102 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin:	noma, Carcinom	a, Basosq. Tumor (M o	r B), Basal Cell Adenoma epithelioma 3/50 (6%)			1/52 (2%)	0/50 (0%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%			
#Skin: Fibroma			5/50 (10%)			2/52 (4%)	0/50 (0%)				
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	2/102 (1.96%)	Mean 1.92%	SD 2.72%			
#Skin: Fibroma, Fibrosarcoma Overall Incidence				SD 0%	Total	2/52 (4%) 2/102 (1.96%)	0/50 (0%) Mean 1.92%	SD 2.72%			
#Skin: Hemangiosarcoma			1/50 (2%)			1/52 (2%)	0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%			
#Skin: Keratoacanthoma			2/50 (4%)			1/52 (2%)	0/50 (0%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 15

			Male		Female							
#Skin: Neural Crest Tumor												
			1/50 (2%)			0/52 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/102 (0%)	Mean 0%	SD 0%				
#Skin: Neurofibrosarcoma or	Schwannoma (m	alignant or NOS)										
	(angham of 1100,	0/50 (0%)			1/52 (2%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%				
Neurofibrosarcoma, Ne	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/52 (2%) 1/102 (0.98%)	0/50 (0%) Mean 0.96%	SD 1.36%				
·	·	, ,	0/50 (0%)	SD 0%	Total	` ,	` '	SD 1.36%				
#Skin: Schwannoma Malignar	nt		0/50 (0%)			1/52 (2%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%				
#Skin: Squamous Cell Papillo	ma, Papilloma, S	quamous Cell Carcino	ma or Keratoacanthoma	ı								
			2/50 (4%)			1/52 (2%)	0/50 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%				
#Skin: Squamous Cell Papillo	ma, Papilloma, o	r Keratoacanthoma										
			2/50 (4%)			1/52 (2%)	0/50 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES **Page:** 16

	Male					Female				
*Testes: Adenoma Overall Incidence	Total	2/50 (///)	2/50 (4%) Mean 4%	SD 0%						
Overali incidence	Total	2/50 (4%)	wean 4%	SD 0%						
*Thyroid Gland: C-Cell: Adenoma			40/50 (000/)			0/54 /400/)	40/50 (00%)			
Overall Incidence	Total	13/50 (26%)	13/50 (26%) Mean 26%	SD 0%	Total	9/51 (18%) 19/101 (18.81%)	10/50 (20%) Mean 18.82%	SD 1.66%		
*Thyroid Gland: C-Cell: Carcinoma										
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	2/51 (4%) 3/101 (2.97%)	1/50 (2%) Mean 2.96%	SD 1.36%		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma			13/50 (26%)			11/51 (22%)	11/50 (22%)			
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	22/101 (21.78%)	Mean 21.78%	SD 0.31%		
*Thyroid Gland: Follicular Cel Adenoma										
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/51 (2%) 1/101 (0.99%)	0/50 (0%) Mean 0.98%	SD 1.39%		
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/51 (2%) 1/101 (0.99%)	0/50 (0%) Mean 0.98%	SD 1.39%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 17

			Male	Female				
#Tooth: Odontoma								
		- (()	0/50 (0%)			1/52 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
#Uterus: Carcinoma								
						2/52 (4%)	1/50 (2%)	
Overall Incidence					Total	3/102 (2.94%)	Mean 2.92%	SD 1.31%
#Uterus: Polyp Stromal								
						3/52 (6%)	8/50 (16%)	
Overall Incidence					Total	11/102 (10.78%)	Mean 10.88%	SD 7.23%
#Uterus: Sarcoma Stromal or Polyp Str	romal							
						3/52 (6%)	8/50 (16%)	25 - 222/
Overall Incidence					Total	11/102 (10.78%)	Mean 10.88%	SD 7.23%
#Uterus: Schwannoma Malignant								
						1/52 (2%)	0/50 (0%)	
Overall Incidence					Total	1/102 (0.98%)	Mean 0.96%	SD 1.36%
#Uterus: Squamous Cell Carcinoma								
						0/52 (0%)	1/50 (2%)	
Overall Incidence					Total	1/102 (0.98%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 18

		Male					Female			
#Vagina: Polyp										
Overall Incidence					Total	1/52 (2%) 1/102 (0.98%)	0/50 (0%) Mean 0.96%	SD 1.36%		
#Vagina: Squamous Cell Carcinoma										
Overall Incidence					Total	1/52 (2%) 1/102 (0.98%)	0/50 (0%) Mean 0.96%	SD 1.36%		
#Zymbal's Gland: Carcinoma										
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/52 (0%) 0/102 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Zymbal's Gland: Carcinoma or Adenoma										
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/52 (0%) 0/102 (0%)	0/50 (0%) Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied